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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,029	07/24/2001	Gabor Bogye	21965	6045

535 7590 10/03/2006

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/890,029	**Applicant(s)** BOGYE, GABOR	
	Examiner San-ming Hui	**Art Unit** 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

San-ming Hui
Primary Examiner
Art Unit: 1617

ADVISORY ACTION

Continuation of 11):

Applicant's amendments filed August 4, 2006 averring the term "healthy patient" being known to one of ordinary skill in the art have been considered, but are not found persuasive. Examiner notes that the claims recite "otherwise healthy patients". Although it is easy to understand what "healthy patients" might be, it is not clear what the term "otherwise healthy patients" refers to. The instant specification does not define what the term really means. The metes and bounds of the claims is therefore, cannot be ascertained by one of ordinary skill in the art.

Applicant's arguments filed August 4, 2006 averring the cited prior arts' failure to teach the patients populations have been considered, but are not found persuasive. Examiner gives the broadest reasonable interpretation to the limitations recited. Patient receiving progestin experience conditions induced by the progestin are considered meeting the limitations herein claimed. Examiner notes that in Butterworth et al., the patients are having cervical hyperplasia induced by taking progestin containing oral contraceptives. Therefore, they are "otherwise healthy patients" because other than the oral contraceptive induced condition, they are healthy female. It is the same way for Spellacy et al. As for Kafrissen et al., it is clearly discloses that the administration of folic acid is for the prevention of disorders preventable by folic acid in patients that are predisposed to such conditions. Examiner notes that patients predisposed to a disorder means that they have not had the disorder; and therefore, they are healthy patients. Accordingly, possessing the teachings of the cited prior arts, one of ordinary skill in the

art would see that the instant claims are anticipated by the teachings of the cited prior arts.

Applicant's arguments filed August 4, 2006 averring the affidavit under 37 CFR 1.131 filed February 9, 2006 have been considered, but are not found persuasive. Examiner notes that for rejection under 35 USC 102(e) can only be overcome by affidavit under 37 CFR 1.131 if the reference is not a U.S. patent or a U.S. patent application publication claiming the same patentable invention. "When the claims of the reference U.S. patent or U.S. patent application publication and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not an acceptable method of overcoming the rejection." See MPEP 706.02 (b). Since Kafrissen is al. claims the same invention with the exact same method steps (i.e., administering the same compounds to the same patient population), the affidavit filed February 9, 2006 cannot be used to overcome such rejection.

Applicant's arguments filed August 4, 2006 averring the cited prior art's failure to disclose the administration of gestagen hormone and its relationship between homocysteins levels and thromboembolism have been considered, but are not found persuasive. The herein claimed invention is directed towards the treatment of elevated homocysteine levels in order to reduce the risk of thromboembolism using old and well-known agents for reducing homocysteine levels due to gestagen hormone. Examiner notes that the herein claimed agents are known to decrease the level of homocysteine, which is responsible for increasing the risk of cardiovascular disorders. Therefore, one of ordinary skill in the art would have been motivated to employ the herein recited

agents to treat the elevated homocysteine levels and thereby reduce the risk of thromboembolism in the same patients, regardless of the cause of elevated homocysteine level. Considering the following example: morphine, an old and well-known analgesic, is known to be effective to treat pain, regardless of what the causes might be, be it cancer related pain, pain due to broken bone, or pain due to kidney stone. These conditions can be effectively treated with morphine since the treatment is directed to pain itself not the etiologies of it. In the same way, the instant invention is to treat elevated homocysteine levels, not the etiologies (e.g., one of which is gestagen hormone according to the instant claim) of it. Therefore, when a patient is presented with elevated homocysteine levels, possessing the cited prior arts, one of ordinary skill in the art would have employed the herein claimed agents in a method of treating hyperhomocysteinemia and thereby reducing the risk of thromboemolism.

No unanswered arguments are seen to be present.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617